IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO., Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	Case No. C. A. No. 07-731

IMPAX LABORATORIES, INC.'S REPLY IN SUPPORT OF ITS MOTION TO STRIKE IMMATERIAL AND IMPERTINENT ALLEGATIONS FROM PLAINTIFFS' COMPLAINT

Mary B. Matterer (I.D. No. 2696)
MORRIS JAMES LLP
500 Delaware Avenue, 15th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800
mmatterer@morrisjames.com

Asim Bhansali
Klaus H. Hamm
KEKER & VAN NEST LLP
710 Sansome Street
San Francisco, CA 94111
Telephone: (415) 391-5400

Attorneys for Defendant
Impax Laboratories, Inc.

Dated: January 25, 2008

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

I. INTRODUCTION

Despite Plaintiffs Endo Pharmaceutical Inc.'s and Penwest Pharmaceutical Co.'s (collectively "Endo") attempt to describe this case as something other than a "straightforward, run-of-the-mill Hatch-Waxman infringement action," that is precisely what it is. The only two counts left in Endo's Complaint are for patent infringement. The Complaint once had another claim related to Endo's theory about why this case is not straightforward, but Endo *voluntarily withdrew that claim*. Endo, however, did not withdraw the allegations that support that claim—and that claim only—so Impax has moved to strike them.

The allegations Impax seeks to strike do not relate to any claims that are left in this case, and instead pertain to an ongoing administrative proceeding before the Food and Drug Administration ("FDA"). Endo argues that these allegations are relevant to its infringement counts because they provide a "background" explanation that Endo was forced to sue for infringement when it did in order to obtain a 30-month stay for the final approval of Impax's competing generic drug. But these "background" allegations are immaterial to question of whether Impax's abbreviated new drug application ("ANDA") infringes Endo's patents. Whether Impax's ANDA is subject to a 30-month stay of approval is the subject of an ongoing proceeding between the FDA and Impax. Endo's apparent motivation in persisting with these allegations is to inject itself into that administrative proceeding by way of this litigation. Not only is this attempt improper, but allowing it to proceed would severely prejudice Impax by forcing it to answer allegations about a matter pending before the FDA.

II. BACKGROUND

A. The 30-month stay applies only if a plaintiff sues on a pre-listed patent.

While an outline of the complex regulatory scheme governing ANDAs is not relevant to the infringement claims set forth in Endo's Complaint, or the Motion to Strike as Impax filed it, this context is necessary for understanding why the arguments in Endo's Opposition that this scheme is relevant fail.

Pharmaceutical companies seeking approval for a generic version of an already approved drug (or "reference drug") may do so by filing an ANDA with the FDA pursuant to the Federal Food, Drug and Cosmetic Act ("FFDCA"). 21 U.S.C. § 355(j). The ANDA must demonstrate that the generic drug it discloses is bioequivalent to the reference drug, thus allowing the ANDA to rely on the safety and efficacy studies performed for the reference drug. 21 U.S.C. § 355(j)(2)(A). Furthermore, the ANDA must contain a certification as to each patent listed in the so-called Orange Book as purportedly covering the reference drug.[1] 21 U.S.C. § 355(j)(2)(A)(vii). If the ANDA filer submits a certification to the FDA under "paragraph IV," the filer asserts that the listed patent(s) are invalid or will not be infringed by the manufacture, use, or sale of the generic drug disclosed in the ANDA. Within 20 days after the ANDA's acceptance by the FDA, the filer must provide a Paragraph IV Notice to the holder of the approved drug application and to the holder of the patents listed in the Orange Book regarding the certification. 21 U.S.C. § 355(j)(2)(B)(i). This notice triggers a 45-day time period for the filing of an infringement suit by the holder of the patents. If this deadline is met, the FDA normally may not approve the ANDA for 30 months unless the patent expires earlier or there is an earlier judicial determination that the patent is not infringed, invalid, or unenforceable. 21 U.S.C. § 355(j)(5)(B)(iii). This 30-month stay applies *only* if the patent was submitted for listing in the Orange Book *before* a "substantially complete" ANDA is filed. *Id.* Within this statutory scheme, the FDA determines whether the 30-month stay will apply, subject to review under the Administrative Procedure Act ("APA"). Likewise, the FDA decides whether the ANDA complies with other requirements for final approval, also subject to review under the APA.

B. Impax's generic oxymorphone ANDA and paragraph IV notices.

On June 29, 2007, Impax submitted an ANDA to the FDA seeking approval for a generic version of Endo's OPANA ER tablets. *See* Ex. 1, Impax's Dec. 17, 2007 press release. After

[1] Parties who receive approval for a drug that has not been previously approved may submit to the FDA a list of patents that they claim covers the drug. Those patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is known as the Orange Book. 21 U.S.C. §§ 355(b)(1) & 355(j)(7)(A)(iii).

accepting this ANDA for filing, the FDA rescinded its acceptance. *See* Ex. 2, Impax's Oct. 4, 2007 press release.

On October 2, 2007, Endo submitted information regarding U.S. Patent No. 7,276,250 ("'250 patent")—which Endo has not alleged Impax infringes—for listing in the Orange Book with respect to OPANA ER tablets, and the FDA listed the patent in the Orange Book. Complaint at ¶ 25. That same day, Impax sent Endo a Paragraph IV Notice regarding the '250 patent. *Id.*

Two weeks later, on October 19, 2007, Endo submitted information regarding the two patents-in-suit—U.S. Patent Nos. 5,662,933 (the "'933 patent") and 5,958,456 (the "'456 patent") for controlled release formulations for the drug albuterol—for listing in the Orange Book with respect to OPANA ER tablets, and the FDA thereafter listed the patents in the Orange Book. *Id.* at ¶ 26. On October 29, 2007, Impax sent Endo a Paragraph IV Notice regarding the '933 and '456 patents. *Id.* at ¶¶ 41-43.

On November 12, 2007, Impax offered to refrain from filing a declaratory judgment action regarding the '250, '933 and '456 patents until December 13, 2007, *i.e.*, 45 days from Impax's Paragraph IV Notices regarding the '933 and '456 patents, and to keep Endo apprised about the status of its ANDA. *See* Ex. 3, November 12, 2007 letter. Endo ignored this offer.

Instead, on November 15, 2007, Endo filed this suit, which accuses Impax of infringing only the '933 and '456 patents. Endo did not file an infringement action of the '250 patent, even though the original Paragraph IV Notice that Endo says forced it to sue was limited to the '250 patent. Endo filed this action only 17 days after Impax provided a Paragraph IV Notice relating to the '933 and '456 patents. In addition, Count I of Endo's Complaint sought declaratory relief that Impax improperly served Paragraph IV Notices because the FDA had rescinded its acceptance of Impax's ANDA. On November 20, Endo filed a Motion for Expedited Declaratory Relief on Count I. Ex. 4, Endo's Mtn. for Expedited Declaratory Relief.

On December 12, 2007—one day before the earliest date Impax said it would file a declaratory judgment action—the FDA informed Impax that it accepted Impax's ANDA for

filing and that it considers November 23, 2007—rather than June 29, 2007—the date that it received an ANDA from Impax that was acceptable for filing and substantive review. *See* Ex. 1, Impax's Dec. 17, 2007 press release. Impax believes that the FDA should determine that Impax had submitted a substantially complete ANDA on June 29, 2007, and this issue remains in front of the FDA. *See id.* On December 13, 2007, Impax sent Endo Paragraph IV Notices for the '250, '933 and '456 patents. *See* Ex. 5, Endo's Dec. 17, 2007 press release.

With the (second) acceptance of its ANDA by the FDA, Impax requested that Endo withdraw Count I and its Motion for Expedited Declaratory Relief as moot. On December 20, 2007, Endo withdrew Count I and its Motion but refused to withdraw the allegations in its complaint that relate only to Count I.

III. ARGUMENT

A. The allegations that Impax moves to strike are irrelevant to the only counts remaining in Endo's Complaint.

1. The allegations do not pertain to infringement.

The allegations at issue are not relevant to the only two counts remaining in Endo's Complaint. First, Endo's Complaint repeatedly refers to the '250 patent even though neither of the remaining counts accuse Impax of infringing the '250 patent. The allegations about the '250 patent are in the Complaint only because Count I sought a declaratory judgment that Paragraph IV Notices served by Impax and related to the '250 patent are null and void. Now that Endo has withdrawn Count I, the allegations about a patent not at issue have no relevance to this action and should be stricken. Second, the Court should strike from Endo's Complaint the extended allegations about how Impax has violated the FFDCA by prematurely sending out Paragraph IV Notices stating that its ANDA does not infringe the '933 or '456 patents. These allegations do not relate at all to the question of whether the filing of Impax's ANDA—which was indisputably accepted for filing by the FDA—infringes the '933 or '456 patents.

2. *Biovail* is not distinguishable.

Biovail Laboratories v. Torpharm, Inc., 2003 WL 21254417, *2 (N.D. Ill. 2003), which held that a court should strike as immaterial allegations regarding the adequacy of Paragraph IV Notices from a complaint alleging patent infringement is directly on point. *Biovail* relied on a Federal Circuit case that held that a court "cannot enforce the requirements of paragraph IV certifications in an infringement suit." *Minnesota Mining and Mfr. Co. v. Barr Laboratories*, 289 F.3d 775, 783 (Fed. Cir. 2002). Endo's attempt to distinguish *Biovail*, on the grounds that the stricken allegations in that case related to the content of a Paragraph IV Notice rather than the right to file one, must fail. The unambiguous prohibition in *Minnesota Mining* did not rest on something peculiar about challenging the *contents* of a Paragraph IV Notice. Instead, the Federal Circuit broadly prohibited private causes of action "under the FFDCA because of another party's failure to comply with [21 U.S.C. § 355(j)(2)(B)]." *Id.* at 783. Thus, challenging a Paragraph IV Notice is prohibited in a patent infringement suit, whatever the grounds for the challenge.[2]

3. The allegations do not provide relevant "background."

Nevertheless, Endo argues that the allegations provide "background" to its infringement claims because they describe why Endo made these claims. Opp'n 9. Even if *Minnesota Mining* did not prohibit Endo from providing this "background" in an infringement action, the allegations do not demonstrate that Endo was forced to file this lawsuit. Endo's argument that it "had no practical choice but to institute this action within 45 days of receiving the first of Impax's improper Paragraph IV Notices, in order to preserve [its] statutory rights under the Hatch-Waxman Act" is particularly misleading. *Id.* at 6. Endo filed this action 44 days after receiving a Paragraph IV Notice regarding the '250 patent, *but Endo has not sued Impax for infringing that patent*. In any case, Endo would not have had a right to a 30-month stay based on Impax's October 3, 2007 Paragraph IV Notice because it referenced an ANDA filed *before* Endo listed the '250 patent in the Orange Book. 21 U.S.C. § 21 U.S.C. § 355(j)(5)(B)(iii).

[2] Endo also suggests that its allegations go to the Court's jurisdiction. These allegations, however, have no merit and Endo has withdrawn Count I and its motion for a judgment on Count I, both of which presented Endo's jurisdictional argument.

Endo sued Impax only 17 days after receiving October 29, 2007 Paragraph IV Notices for the two patents that are actually part of this action. Moreover, if Endo is correct that Impax's October 29 Paragraph IV Notices are void, the 45-day clock for filing suit on these patents did not start until December 13, 2007 when Impax served Paragraph IV Notices after the FDA informed Impax that it had accepted its ANDA for filing. Moreover, Impax had unilaterally offered not to sue for declaratory judgment any earlier than December 13, 2007. Nor did Endo need to file to protect itself in the event that it was wrong. If the October 29, 2007 Paragraph IV Notices were valid, then Impax had a "substantially complete" ANDA on file *before* Endo listed the patents in the Orange Book and the 30-month stay was not available in first place. 21 U.S.C. § 21 U.S.C. § 355(j)(5)(B)(iii).[3]

4. Endo's allegations do not relate to its claim that this is an exceptional case.

Endo's attempt to conjure up relevance for the allegations at issue by claiming they relate to its claim that this is an exceptional case also fails because Paragraph IV Notices can support an exceptional case claim only when the notices do not put forward a colorable non-infringement or invalidity position. The Federal Circuit has emphasized that "conduct may give rise to an award of attorney's fees" in ANDA infringement actions in extremely limited circumstances. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350 (Fed. Cir. 2004). Endo relies on a line of cases that hold that inadequate content in a Paragraph IV Notice, combined with litigation misconduct, can support a finding that an ANDA action is an exceptional case. *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmcal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000) ("notice does not present a *prima facie* case of invalidity" or reference the drug's "potency, safety, and lack of side effects"); *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, 2005 WL 3664014 (D. N.J. 2005) (regarding allegations that alleged infringer "failed to provide the required detailed statement and legal basis in its notice letter"). Unlike the patent holders in *Yamanouchi* and

[3] Endo's further argument that its allegations are relevant because it made its patent claims "expressly in the alternative," only highlights the allegations' irrelevance. Opp'n 9. Now that Endo has voluntarily dismissed Count I, its infringement claims are the only ones in its Complaint, making it impossible for them to be "in the alternative." While the allegations once related to an alternative count in the Complaint, they now relate to a count that no longer exists.

Novartis, Endo does *not* challenge the robustness of Impax's Paragraph IV Notices. Endo, in fact, goes out of its way to point out that Endo's "allegations do not relate to the substantive content of Impax's Notices." Opp'n 10 n.2. Instead, Endo challenges only their timing, alleging that Impax made them prematurely. While a party can obtain a declaration that a case is exceptional because the ANDA filer could not present even a *prima facie* argument of non-infringement or invalidity to support a Paragraph IV certification, no precedent exists supporting the notion that a case is exceptional because the parties had a disagreement about the *timing* of a regulatory event, an issue that is still being resolved by the FDA.[4]

B. Impax will suffer prejudice if allegations about its conduct before the FDA remain in the case.

Impax still has administrative issues before the FDA regarding matters related to the allegations it seeks to strike here. At this juncture, *only* the FDA may consider them. As mentioned above, the FFDCA prohibits private actions to enforce its requirements, and the Federal Circuit has held that a court "cannot enforce the requirements of paragraph IV certifications in an infringement suit." 21 U.S.C. § 337(a); *Minnesota Mining*, 289 F.3d at 783, 784 n.5. In addition, the ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.'" *Disabled American Veterans v. Gober*, 234 F.3d 682, 690-91 (Fed. Cir. 2000) (quoting *Abbott Labs. v. Gardner,* 387 U.S. 136, 148-49, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967)). Forcing Impax to respond to allegations that may not now be presented in federal court will prejudice Impax, especially when Impax is adjudicating these same issues before the FDA.

[4] Endo's argument that the allegations at issue in its Complaint are relevant because they relate to Impax's Counterclaims rely entirely on the mistaken premise that Impax's Counterclaims depend on 35 U.S.C. § 271(e)(5) for jurisdiction. That statute provides jurisdiction for ANDA filers to seek declaratory relief regarding patents listed in the Orange Book when the patent holder has not filed an infringement action within 45 days. As set forth in paragraph 77 of Impax's Counterclaims, this Court has declaratory judgment jurisdiction under 28 U.S.C. § 2201. Indeed, application of this jurisdictional statute is incredibly straightforward in this case because Endo's infringement against Impax regarding the patents-in-suit creates an "actual controversy."

IV. CONCLUSION

For the foregoing reasons, Impax requests that this Court grant its motion to strike the irrelevant allegations from Endo's Complaint.

Mary B. Matterer (I.D. No. 2696)
MORRIS JAMES LLP
500 Delaware Avenue, 15th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800
mmatterer@morrisjames.com

Asim Bhansali
Klaus H. Hamm
KEKER & VAN NEST LLP
710 Sansome Street
San Francisco, CA 94111
Telephone: (415) 391-5400

Attorneys for Defendant
Impax Laboratories, Inc.

Dated: January 25, 2008

EXHIBIT 1

Press Release

IMPAX Announces FDA Acceptance of ANDA for Generic Version of Opana(R) ER

HAYWARD, Calif.--(BUSINESS WIRE)--Dec. 17, 2007--IMPAX Laboratories, Inc. (OTC:IPXL) today announced that its Abbreviated New Drug Application (ANDA) for oxymorphone hydrochloride extended-release tablets CII, a generic version of Opana(R) ER, has been deemed acceptable for filing by the U. S. Food and Drug Administration (FDA) as of November 23, 2007. Despite the acceptance, the Company continues to believe that its ANDA as originally filed met all the requirements for acceptance and thus will continue to pursue its administrative remedies with the FDA to reinstate its original filing date of June 29, 2007.

"We also intend to continue to vigorously defend the ongoing patent litigation as previously announced with Endo and Penwest and look forward to prevailing and bringing this important generic product to market," said Larry Hsu, Ph.D., IMPAX's president and chief executive officer.

About IMPAX Laboratories, Inc.

IMPAX Laboratories, Inc. is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of branded products. IMPAX markets its generic products through its Global Pharmaceuticals division and markets its branded products through the IMPAX Pharmaceuticals division. Additionally, where strategically appropriate, IMPAX has developed marketing partnerships to fully leverage its technology platform. IMPAX Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward and Philadelphia facilities. For more information, please visit the Company's Web site at: www.impaxlabs.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

To the extent any statements made in this news release contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause IMPAX's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, possible adverse effects resulting from the delisting of and suspension of trading in IMPAX's stock, the SEC proceeding to determine whether to suspend or revoke the registration of IMPAX's securities under section 12 of the Securities Exchange Act, IMPAX's delay in filing its 2004 Form 10-K, its Form 10-Q for each of the first three quarters of 2005, 2006, and 2007, its Form 10-K for 2005 and 2006, the actual time that will be required to complete the filing of IMPAX's delinquent periodic reports, IMPAX's ability to obtain sufficient capital to fund its operations, the difficulty of predicting FDA filings and approvals, consumer acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, IMPAX's ability to successfully develop and commercialize pharmaceutical products, IMPAX's reliance on key strategic alliances, the uncertainty of patent litigation, the availability of raw materials, the regulatory environment, dependence on patent and other protection for innovative products, exposure to product liability claims, fluctuations in operating results and other risks detailed from time to time in IMPAX's filings with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and IMPAX undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

CONTACT: IMPAX Laboratories, Inc. Larry Hsu, Ph.D., President & CEO, 510-476-2000, x1111 Arthur Koch, CFO, 215-933-0351 www.impaxlabs.com or Investor Relations Contacts: Lippert/Heilshorn & Associates, Inc. Kim Sutton Golodetz, 212-838-3777 kgolodetz@lhai.com Bruce Voss, 310-691-7100 bvoss@lhai.com www.lhai.com SOURCE: IMPAX Laboratories, Inc.

EXHIBIT 2

Print Page Close Window

Press Release

IMPAX Comments on Status of ANDA for Generic Opana(R) ER

HAYWARD, Calif., Oct 04, 2007 (BUSINESS WIRE) -- IMPAX Laboratories, Inc. (OTC:IPXL) today confirmed reports that it has provided notice to Endo Pharmaceuticals Holdings Inc. and Penwest Pharmaceuticals Co. that it has submitted an Abbreviated New Drug Application (ANDA) for oxymorphone hydrochloride extended-release tablets CII, generic of Opana (R) ER, to the U.S. Food and Drug Administration (FDA). IMPAX's ANDA, as amended, contains a Paragraph IV certification stating that the Company believes its product does not infringe US Patent No. 7,276,250, or that the patent is invalid or unenforceable. Following an acceptance for filing by the FDA the Company was informed by the agency that it has rescinded its initial acceptance. IMPAX believes that the rescission is inappropriate and is working with the FDA to correct any deficiencies of the ANDA.

Endo Pharmaceuticals Holdings Inc. and Penwest Pharmaceuticals Co. manufacture and market Opana ER for the treatment of moderate to severe pain. According to Wolters Kluwer Health, U.S. sales of Opana ER tablets were approximately $42.9 million in the 12 months ended August 31, 2007.

About IMPAX Laboratories, Inc.

IMPAX Laboratories, Inc. is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of branded products. IMPAX markets its generic products through its Global Pharmaceuticals division and markets its branded products through the IMPAX Pharmaceuticals division. Additionally, where strategically appropriate, IMPAX has developed marketing partnerships to fully leverage its technology platform. IMPAX Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward and Philadelphia facilities. For more information, please visit the Company's Web site at: www.impaxlabs.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

To the extent any statements made in this news release contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause IMPAX's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, possible adverse effects resulting from the delisting of and suspension of trading in IMPAX's stock, the SEC proceeding to determine whether to suspend or revoke the registration of IMPAX's securities under section 12 of the Securities Exchange Act, IMPAX's delay in filing its 2004 Form 10-K, its Form 10-Q for each of the first three quarters of 2005 and 2006, its Form 10-K for 2005 and 2006, and its Form 10-Q for the first quarter of 2007, the actual time that will be required to complete the filing of IMPAX's delinquent periodic reports, IMPAX's ability to obtain sufficient capital to fund its operations, the difficulty of predicting FDA filings and approvals, consumer acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, IMPAX's ability to successfully develop and commercialize pharmaceutical products, IMPAX's reliance on key strategic alliances, the uncertainty of patent litigation, the availability of raw materials, the regulatory environment, dependence on patent and other protection for innovative products, exposure to product liability claims, fluctuations in operating results and other risks detailed from time to time in IMPAX's filings with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and IMPAX undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

SOURCE: IMPAX Laboratories, Inc.

Company Contacts:
IMPAX Laboratories, Inc.
Larry Hsu, Ph.D. President & CEO
510-476-2000, Ext. 1111

Arthur A. Koch, Jr. CFO
215-933-0351
www.impaxlabs.com
or
Investor Relations Contacts:
Lippert/Heilshorn & Associates, Inc.
Kim Sutton Golodetz, 212-838-3777
kgolodetz@lhai.com
Bruce Voss, 310-691-7100
bvoss@lhai.com
www.lhai.com

EXHIBIT 3

LAW OFFICES
KEKER & VAN NEST
LLP
710 SANSOME STREET
SAN FRANCISCO, CA 94111-1704
TELEPHONE (415) 391-5400
FAX (415) 397-7188
WWW.KVN.COM

ASIM M. BHANSALI
ABHANSALI@KVN.COM

November 12, 2007

VIA FACSIMILE

George Gordon
Dechert LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104

Robert J. Gunther, Jr.
WilmerHale
399 Park Avenue
New York, NY 10022

Re: Impax Oxymorphone ANDA

Dear George and Robert:

I write to follow up on my November 7 letter to George and my November 8 discussion with George.

For the reasons set forth in its Notice letters, Impax firmly believes that its ANDA does not infringe any of the patents to which it has made P-IV certifications (U.S. Patent Nos. 5,662,933; 5,958,456; 7,276,250, collectively the "Listed Patents"). Therefore, Impax wishes to provide Endo and Penwest sufficient time to evaluate the ANDA excerpts that Impax has provided. Impax believes that this evaluation will lead Endo and Penwest to the conclusion that the ANDA does not infringe any of the Listed Patents. Impax requests that upon concluding review of the ANDA materials, Endo and Penwest provide it with a perpetual covenant not to sue for infringement of the Listed Patents by the ANDA or any products made pursuant to the ANDA.

To provide Endo and Penwest comfort while you evaluate infringement, Impax will provide the following information and take the following steps:

1. If the FDA makes a determination regarding the date upon which it treats Impax ANDA as accepted, Impax will promptly disclose that date to you. Impax reserves its right to challenge the FDA's determination, if the FDA determines a date other than Impax's original ANDA filing date. Impax also reserves the right to file a P-IV certification(s) following any determination of a new acceptance date by the FDA.

2. Impax will not file, prior to the earlier of (1) Impax's serving a new P-IV notice in response to a FDA determination that Impax's ANDA is accepted for filing on a date other than its original filing date; or (2) December 13, 2007, an action for declaratory relief that the ANDA does not infringe the Listed Patents or that the Listed Patents are invalid or unenforceable.

As you are undoubtedly aware, Endo and Penwest could not obtain a 30-month stay by filing suit in response to the P-IV filings that Impax has already made because all the Listed Patents were listed in the Orange Book after Impax filed its ANDA. Impax is offering the accommodations I've described above because Impax believes a good-faith evaluation will lead Endo and Penwest to agree the ANDA does not infringe, and therefore to grant Impax's request for a covenant not to sue on the Listed Patents.

Please do not hesitate to call me if you would like to discuss this matter further.

Sincerely,

ASIM M. BHANSALI

AMB/gap

LAW OFFICES
KEKER & VAN NEST
LLP
710 SANSOME STREET
SAN FRANCISCO, CA 94111-1704
TELEPHONE (415) 391-5400
FAX (415) 397-7188

FACSIMILE TRANSMISSION COVER SHEET

November 12, 2007

To	Telephone	Facsimile
George Gordon Dechert LLP	(215) 994-2382	(215) 994-2222
Robert J. Gunther, Jr. WilmerHale	(212) 230-8830	(212) 230-8888
From	**Telephone**	**Code**
Asim M. Bhansali	(415) 773-6608	**6171/GAP**

Re ***Abbott Laboratories, et al. v. Teva Pharmaceuticals, et al.***
USDC, Dist. of Delaware, Case No. 02-1512-KAJ

Number of Pages (Including Cover): 3

ORIGINAL WILL NOT FOLLOW THIS TRANSMISSION

COMMENTS

Please see attached correspondence.

Operator _____ Time Sent _____

IF YOU ENCOUNTER ANY DIFFICULTIES RECEIVING THIS TRANSMISSION, PLEASE CALL (415) 676-2277 OR (415) 391-5400

354205.01

EXHIBIT 4

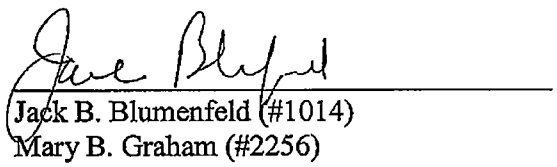
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-731
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

PLAINTIFFS' MOTION FOR
EXPEDITED DECLARATORY JUDGMENT RELIEF

Pursuant to Federal Rule of Civil Procedure 57, Plaintiffs Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. hereby move this Court for expedited declaratory judgment relief in the form of the attached Order. The grounds for this Motion are fully set forth in the accompanying Opening Brief.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)
Mary B. Graham (#2256)
Julia Heaney (#3052)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mgraham@mnat.com
jheaney@mnat.com

Attorneys for Plaintiffs
Endo Pharmaceuticals Inc. and
Penwest Pharmaceuticals Co.

Of Counsel:

Martin J. Black
George G. Gordon
Ann M. Caviani Pease
Robert D. Rhoad
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
(215) 994-4000

Robert J. Gunther, Jr.
Lisa J. Pirozzolo
James P. Barabas
WILMER CUTLER PICKERING HALE AND DORR LLP
399 Park Avenue
New York, NY 10022
(212) 230-8800

November 20, 2007

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-731
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

ORDER

AND NOW, this _____ day of _____, 2007, upon consideration of Plaintiffs' Motion for Expedited Declaratory Judgment Relief, and any response thereto, IT IS HEREBY ORDERED that:

(1) Plaintiffs' motion is GRANTED;

(2) With respect to Count I of the Complaint, the Court declares that:

A. Impax's Paragraph IV Notices are null, void and without legal effect, and Impax was not entitled to trigger the ANDA patent litigation process with respect to United States Patent No. 7,276,250 ("the '250 patent"), United States Patent No. 5,662,933 ("the '933 patent"), or United States Patent No. 5,958,456 ("the '456 patent");

B. This Court has no subject matter jurisdiction over claims between Plaintiffs and Impax regarding infringement of the '250, '933 or '456 patents because the Paragraph IV Notices served by Impax are null, void and without legal effect;

C. The Paragraph IV Notices served by Impax did not commence the 45-day period for filing a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); and

D. If and when the FDA accepts Impax's ANDA for substantive review, Impax must submit and serve on Endo and Penwest at that time new Paragraph IV Certifications and Notices pursuant to 21 U.S.C. § 355(j)(2)(A)(vii).

(3) In light of the above declarations, Counts II and III of the Complaint are dismissed without prejudice as moot.

BY THE COURT:

_____

J.

EXHIBIT 5

News Release

Print This Page Back

Endo and Penwest Receive New Paragraph IV Certification Notice From IMPAX for OPANA(R) ER

CHADDS FORD, PA and DANBURY, CT, Dec 17, 2007 (MARKET WIRE via COMTEX News Network) -- Endo Pharmaceuticals Holdings Inc. (NASDAQ: ENDP) and Penwest Pharmaceuticals Co. (NASDAQ: PPCO) announced today that on December 14, 2007, they received a notice from IMPAX Laboratories, Inc. advising of the FDA's acceptance for substantive review, as of November 23, 2007, of IMPAX's Abbreviated New Drug Application (ANDA) containing a new Paragraph IV certification under 21 U.S.C. Section 355(j) for oxymorphone hydrochloride extended-release tablets CII. IMPAX stated in its letter that the FDA requested IMPAX to provide notification to Endo and Penwest of this certification. This Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933, which cover the formulation of OPANA(R) ER. These patents are listed in the FDA's Orange Book and expire in 2022, 2013 and 2013, respectively. In addition to these patents, OPANA ER has a new dosage form (NDA) exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on June 22, 2009.

Endo and Penwest are currently reviewing the details of this new notice from IMPAX and will continue to pursue all available legal and regulatory avenues in defense of OPANA ER, including enforcement of their intellectual property rights and approved labeling.

About Endo

Endo Pharmaceuticals Holdings Inc. is a fully integrated specialty pharmaceutical company with market leadership in pain management products. Through its Endo Pharmaceuticals Inc. subsidiary, the company researches, develops, produces and markets a broad product offering of both branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. More information, including this and past press releases of Endo Pharmaceuticals Holdings Inc., is available online at www.endo.com.

Endo Forward-Looking Statement

This press release contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on management's beliefs and assumptions, current expectations, estimates and projections. Statements that are not historical facts, including statements which are preceded by, followed by, or that include, the words "believes," "anticipates," "plans," "expects" or similar expressions and statements are forward-looking statements. Endo's estimated or anticipated future results, product performance or other non-historical facts are forward-looking and reflect Endo's current perspective on existing trends and information. Many of the factors that will determine the Company's future results are beyond the ability of the Company to control or predict. These statements are subject to risks and uncertainties and, therefore, actual results may differ materially from those expressed or implied by these forward-looking statements. The reader should not rely on any forward-looking statement. The Company undertakes no obligation to update any forward-looking statements whether as a result of new information, future events or otherwise. Several important factors, in addition to the specific factors discussed in connection with these forward-looking statements individually, could affect the future results of Endo and could cause those results to differ materially from those expressed in the forward-looking statements contained in this press release. Important factors that may affect future results include, but are not limited to: market acceptance of the Company's products and the impact of competitive products and pricing; dependence on sole source suppliers; the success of the Company's product development activities and the timeliness with which regulatory authorizations and product launches may be achieved; successful compliance with extensive, costly, complex and evolving governmental regulations and restrictions; the availability on commercially reasonable terms of raw materials and other third party manufactured products; exposure to product liability and other lawsuits and contingencies; dependence on third party suppliers, distributors and collaboration partners; the ability to timely and cost effectively integrate acquisitions; uncertainty associated with pre-clinical studies and clinical trials and regulatory approval; uncertainty of market acceptance of new products; the difficulty of predicting FDA approvals; risks with respect to technology and product development; the effect of competing products and prices; uncertainties regarding intellectual property protection; uncertainties as to the outcome of litigation; a determination by a regulatory agency that we are engaging in inappropriate sales or marketing activities, including promoting the "off-label" use of our products; changes in operating results; impact of competitive products and pricing; product development; changes in laws and regulations; customer demand; possible future litigation; availability of future financing and reimbursement policies of government and private health insurers and others; and other risks and uncertainties detailed in Endo's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K filed with the SEC on March 1, 2007. Readers

should evaluate any statement in light of these important factors.

About Penwest Pharmaceuticals

Penwest is a drug development company dedicated to bringing to the marketplace innovative products that help improve the lives of patients. The Company's goal is to identify, develop and commercialize prescription products that address unmet medical needs, primarily for diseases of the nervous system. Penwest is currently applying its drug delivery and drug development expertise to a pipeline of potential products that are in various stages of development and that it intends to commercialize independently or through third party alliances.

Penwest Forward-Looking Statement

The matters discussed herein contain forward-looking statements that involve risks and uncertainties, which may cause Penwest's actual results in future periods to be materially different from any future performance suggested herein. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "intends," "potential" and similar expressions are intended to identify forward-looking statements. Important factors that could cause results to differ materially include: risks relating to the commercial success of Opana ER and our reliance on Endo for the commercial success of Opana ER, regulatory risks relating to drugs in development, including the timing and outcome of regulatory submissions and regulatory actions; uncertainty of success of collaborations; the timing of clinical trials, including the impact of enrollment rates; whether the results of clinical trials will warrant further clinical trials, warrant submission of an application for regulatory approval of, or warrant the regulatory approval of, the product that is the subject of the trial; whether the patents and patent applications owned by Penwest will protect the Company's products and technology and prevent others from infringing it; actual and potential competition; the need for capital; and other risks as set forth under the caption Risk Factors in Penwest's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 8, 2007, which risk factors are incorporated herein by reference.

The forward-looking statements contained in this press release speak only as of the date of the statement made. Penwest disclaims any intention or obligation to update any forward-looking statements.

SOURCE: Endo Pharmaceuticals